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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,363	02/29/2000	Paul B. Fisher	60849.JPW JML	1657

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EXAMINER
LOEB, BRONWEN

ART UNIT	PAPER NUMBER
1636	20

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/515,363	FISHER ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *12-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 February 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Notice of References Cited	Application/Control No. 09/515,363	Applicant(s)/Patent Under Reexamination FISHER ET AL.	
	Examiner Bronwen M. Loeb	Art Unit 1636	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Brenner (1999) Trends in Genetics 15:132-133
	V	Doerks (1998) Trends in Genetics 14:248-250
	W	Scott et al (1999) Nature Genetics 21:440-443
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

DETAILED ACTION

This action is in response to the amendment filed 16 January 2002. It is noted that the transmittal letter accompanying the filing of the application indicated that a Preliminary Amendment was filed. No such amendment has been found in the file.

Claims 1-30 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 19 is acknowledged.

2. Claims 12-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Drawings

3. The drawings are objected to because apparent Figure 9 is not labeled accordingly. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The Brief Description of Figure 1 recites "SEQ ID No" but does not actually provide the number.

On p. 17, there are recitations of "SEQ ID No" however no number is actually provided. Figure 3 has two panels however the Brief Description of the Drawings does not reflect this. It would be remedial to amend the specification on p. 4, line 32 to read "Figures 3A-3B".

Appropriate correction is required.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The elected claims are not drawn to a promoter.

Sequence Compliance

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, were not listed in the paper sequence that was filed, were not listed in the computer readable format (CRF) that was filed and were not subject to the attorney statement that was filed. These sequences include **Figures 1A, 1B, 1C, 1D and 10**. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-11 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

Claims 1-11 are drawn to an isolated nucleic acid of SEQ ID No. 1, derivatives or fragments of this nucleic acid having functional homology to the polypeptide encoded by SEQ ID No. 1, nucleic acids that hybridize to SEQ ID No. 2, vectors comprising any of these nucleic acids and cells comprising the vectors. The specification discloses the nucleic acid sequence encoding a polypeptide called Mda-5. The specification discloses that expression of this nucleic acid sequence increases in HO-1 melanoma cells treated with interferon-β (IFN-β) and mezerein (MEZ) an antileukemic compound; this treatment induces the terminal differentiation of this immortal cell line. Treatment with IFN-β alone does not induce terminal differentiation, although it does induce expression of mda-5. It is also disclosed that IFN-β induces mda-5 expression in other cells, including normal cerebellum cells and glioblastoma multiforme cells; there is no disclosure of the actual activity or function of Mda-5 in those cells. Based on sequence homologies to known proteins, the specification speculates that Mda-5 protein may function as an RNA helicase (see for instance p., 70, line 32-p. 73, line 9). As one of skill in the art is well aware, homology is a good *starting point* for determining function of a protein however activity or function of a polypeptide based on homology data is simply

not predictive of function. See for instance Brenner (TIG (1999) 15:132-133; Doerks (TIG (1998) 14:248-250 and Scott et al (Nature Genetics (1999) 21:440-443). Based on what types of molecules induce its expression, there is speculation it may function as a cell growth suppressor, in apoptosis or has some undefined anti-viral activity (see for instance p. 74, lines 8-33). Absent concrete evidence of the function for the polypeptide encoded by SEQ ID No. 1, the specification lacks a specific utility for the claimed nucleic acids, vectors comprising the nucleic acids and host cells comprising the vectors. One of skill in the art would need to prepare, purify and analyze the encoded polypeptide encoded by the isolated nucleic acid in order to ascertain the specific function of the encoded polypeptide. Once a specific function has been determined, one would then have to ascertain a use. Therefore the claimed invention is not in a readily available form. Instead, further experimentation on the encoded polypeptide would be required before the claimed nucleic acids could be used in a specific utility.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 2-11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 64, Number 244, Pages 71427-71440). Claim 2 is drawn to an isolated nucleic acid comprising a derivative of SEQ ID No. 1 encoding a polypeptide which is functionally equivalent to Mda-5. This is a genus claim in terms of any derivative of SEQ ID No. 1 encoding a polypeptide which is functionally equivalent to Mda-5. Claim 3 is drawn to a fragment of SEQ ID No. 1 encoding a polypeptide having Mda-5 biological activity. This is a genus claim in terms of any fragment of SEQ ID No. 1 having Mda-5 biological activity. Claim 4 is drawn to a nucleic acid which hybridizes to SEQ ID No. 1 or a complementary strand thereof. This is a genus claim in terms of any nucleic acid that hybridizes to SEQ ID No. 1. The specification mentions only SEQ ID No.1. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all of isolated nucleic acids based on the teachings in the specification. The specification defines "derivative" as including substitutions, insertions, deletions and alterations. Given that the inventors do not know the function of the Mda-5 polypeptide other than speculation based on some homologous motifs, there is no structure-function correlation taught. Therefore, the specification does not describe the claimed isolated nucleic acid fragments, derivatives or hybridizable nucleic acids in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these isolated nucleic acid

fragments, derivatives or hybridizable nucleic acids at the time of filing the present application. Thus, the written description requirement has not been satisfied.

12. Claims 1-11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to an isolated nucleic acid comprising SEQ ID No. 1. Claim 2 is drawn to an isolated nucleic acid comprising a derivative of SEQ ID No. 1 encoding a polypeptide which is functionally equivalent to Mda-5. Claim 3 is drawn to a fragment of SEQ ID No. 1 encoding a polypeptide having Mda-5 biological activity. Claim 4 is drawn to a nucleic acid which hybridizes to SEQ ID No. 1 or a complementary strand thereof. The specification does not disclose the biological function of Mda-5. As discussed above, there is speculation on its function based on sequence homology however it is well known to one of skill in the art that homology alone cannot determine function. There is speculation that it has growth inhibitory action, apoptotic activity and/or anti-viral activity based on the observation that its expression is induced by TNF, poly IC and IFN-β. However, there is no established nexus between the nucleic acid sequences claimed and any of these speculated functions. Consequently, neither the specification nor the prior art teach how to use any of these claimed nucleic acids.

13. The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 2 and 5-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite in reciting the phrase "functional homology". While the specification appears to define functional homology (p. 32-. 33), in the absence of concrete knowledge of what the function is, one cannot determine homology and thus cannot determine the metes and bounds of the claim.

Conclusion

Claims 1-11 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

February 10, 2002

REMY YUCEL, PH.D
PRIMARY EXAMINER